

REMARKS

The Office Action dated May 12, 2008, has been received and carefully considered. In this response claims 1, 2, 6, 8, 9, 11, 12, 16, 17, 19, 21, and 23-25 have been amended. No new matter has been added. Entry of the amendments to the claims 1, 2, 6, 8, 9, 11, 12, 16, 17, 19, 21, and 23-25 is respectfully requested. Reconsideration of the outstanding rejections in the present application is also respectfully requested based on the following remarks.

I. THE OBVIOUSNESS REJECTION OF CLAIMS 1-21 AND 23-30

On page 9 of the Office Action, claims 1-21 and 23-30 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,650,932 to Menzie et al. ("Menzie") in view of U.S. Patent Application Publication No. 2004/0044274 to Bardy ("Bardy") and further in view of U.S. Patent No. 6,223,164 to Seare et al. ("Seare"). This rejection is hereby respectfully traversed.

Under 35 U.S.C. § 103, the Patent Office bears the burden of establishing a prima facie case of obviousness. In re Fine, 837 F.2d 1071, 1074 (Fed. Cir. 1988). There are four separate factual inquiries to consider in making an obviousness determination: (1) the scope and content of the prior art; (2) the level of ordinary skill in the field of the invention; (3)

the differences between the claimed invention and the prior art; and (4) the existence of any objective evidence, or "secondary considerations," of non-obviousness. Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966); see also KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727 (2007). An "expansive and flexible approach" should be applied when determining obviousness based on a combination of prior art references. KSR, 127 S. Ct. at 1739. However, a claimed invention combining multiple known elements is not rendered obvious simply because each element was known independently in the prior art. Id. at 1741. Rather, there must still be some "reason that would have prompted" a person of ordinary skill in the art to combine the elements in the specific way that he or she did. Id.; In re Icon Health & Fitness, Inc., 496 F.3d 1374, 1380 (Fed. Cir. 2007). Also, modification of a prior art reference may be obvious only if there exists a reason that would have prompted a person of ordinary skill to make the change. KSR, 127 S. Ct. at 1740-41.

The Examiner asserts that Menzie substantially discloses the claimed invention. However, Menzie issued November 18, 2003, from U.S. Patent Application No. 09/750,683, filed May 15, 2000. Thus, Menzie has an effective filing date of May 15, 2000.

Applicants again respectfully submit that the invention disclosed and claimed in the present application was conceived

prior to May 15, 2000. Applicants also respectfully submit that they were duly diligent in preparing and filing the present application from the date of conception of the invention disclosed and claimed in the present application to the filing date of the present application (i.e., November 20, 2001). Applicants have supported and continue to support the above-stated submissions with inventor declarations under 37 C.F.R. § 1.131 and supplemental inventor declarations under 37 C.F.R. § 1.131, which contain a showing of facts that clearly establish the above-stated submissions.

At this point it should be noted that the actual date of conception need not be provided (and may be redacted, as Applicants have done) in a declaration, but actual dates of diligence must be provided (which Applicants have provided) (see MPEP 715.07).

In view of the foregoing, Applicants respectfully submit that Menzie is not a proper prior art reference for application against the claims of the present application.

Moreover, regarding claims 1, 11, 19, 24, and 25, the Examiner asserts that the claimed invention would have been obvious in view of Menzie, Bardy, and Seare. Applicants respectfully disagree. However, in order to forward the present application toward allowance, Applicants has amended claims 1, 11, 19, 24, and 25 to more specifically define the claimed

invention, and specifically those features that differentiate the claimed invention from Menzie, Bardy, and Seare, as well as the other cited references. In particular, Applicants respectfully submit that Menzie, Bardy, and Seare, either taken alone or in combination, fail to disclose, or even suggest, a method for collecting and reporting outcomes data for benchmarking medical procedures comprising the steps of: "collecting second outcomes data sets for the one or more indicators associated with the one or more medical procedures for the plurality of individuals in a second period of time via the one or more user interfaces located at the one or more user entities," and "converting at least some of the second outcomes data sets for the one or more indicators associated with one of the one or more medical procedures for the plurality of individuals into at least one second outcomes result," as presently claimed.

Regarding Menzie, Menzie relates to an individual patient's clinical condition, and a technical device for directly viewing the physiological patient data. In contrast, the present application relates to a decision analysis system that tracks comparative patient data over time (e.g., months or years) in order to draw inferences about the quality of the clinical care provided by ambulatory surgery centers in the out-patient surgery environment. More specifically, Menzie fails to

disclose, or even suggest, collecting outcomes data sets associated with a medical procedure for a plurality of individuals (e.g., patients), as set forth in independent claims 1, 11, 19, 24 and 25. Rather, Menzie discloses multiple collection devices 132a-n connected to two processing centers 140 and 142. The Examiner merely alleges that the "system is able to collect numerous patients/individuals information." However, no support can be found for such allegation in Menzie. Furthermore, Menzie discloses a single patient and a single visit or a single clinical episode captured via a single display screen. In contrast, the present application discloses capturing multiple patient visits displayed on multiple display screens. Also, Menzie fails to disclose or even suggest "a medical procedure," as recited in independent claims 1, 11, 19, 24 and 25. Menzie merely discloses that heart rate variability monitors perform signal analysis on physiological signals, and fails to disclose "a medical procedure."

It is also respectfully submitted that Menzie fails to disclose, or even suggest, a method for collecting and reporting outcomes data for benchmarking medical procedures comprising the steps of: "establishing a norm based at least in part on an outcomes data group, wherein the outcomes data group comprises a plurality of the first outcomes data sets," as recited in independent claims 1, 11, 19, 24 and 25. Instead, Menzie merely

discloses a value of 40 mmHg and fails to disclose or even suggest that the 40 mmHg value is established "based at least in part on an outcomes data group." The Examiner relies on column 7, lines 30-31 of Menzie to disclose "establishing a norm based at least in part on an outcomes data group," as presently claimed. Applicants respectfully submit that the Examiner erred in interpreting the teaching of Menzie. In contrast, Menzie discloses "the operator is provided with guidelines for accepting or rejecting the test data." See, e.g., column 7, lines 7-8. Menzie further discloses that "the operator may be instructed that substantial compliance with the desired breathing regimen requires that four of every six breathes fall between the deep breathing maximum value 78 and the deep breathing minimum value 80." See, e.g., column 7, lines 24-28. Therefore, Menzie discloses providing instructions and/or guidelines for an operator to accept or reject the test data and not "establishing a norm based at least in part on an outcomes data group," as presently claimed.

It is further respectfully submitted that Menzie fails to disclose, or even suggest, "comparing a selected one of the at least one second outcomes result to the norm," as presently claimed. The Examiner relies on column 6, lines 29-36 and lines 60-67, to disclose such claimed limitation. However these specific references in Menzie disclose that "a breathing

performance waveform illustrating parameters of the patient's breathing during the collection of physiological data for each test is displayed on display 36 to the operator of the monitor 14 in order to permit an assessment to be made as to how well the particular test was performed." See, e.g., column 6, lines 21-26. Thus, Menzie discloses only accepting the raw physiological data during well-performed testing to improve the accuracy of the test results and not "comparing a selected one of the at least one second outcomes result to the norm," as presently claimed. Also, Menzie does not disclose, or even suggest, calculations or comparisons with other patients, but rather only with one patient. Further, Menzie does not disclose, or even suggest, calculations or comparisons with other medical procedures, but rather only that heart rate variability monitors perform signal analysis on physiological signals. Further, Menzie does not disclose, or even suggest, calculations or comparisons with other organizations, but rather only with one organization at a time. Indeed, Menzie does not disclose, or even suggest, a medical benchmarking system in any manner. In contrast, the present application discloses making benchmark (comparison) calculations across multiple patients for multiple medical procedures for the purpose of comparing multiple organizations. The present application claims the broader application to any unit of observation (e.g., patient)

for any type of activity (e.g., procedure) for any outcome (e.g., indicator), across any organization (e.g., ambulatory surgery center).

Regarding Bardy, the Examiner asserts that Bardy discloses establishing a norm based at least in part on an outcomes data group, wherein the outcomes data group comprises a plurality of the first outcomes data sets for the one or more indicators associated with one of the one or more medical procedures for the plurality of individuals, as set forth in independent claims 1, 11, 19, 24 and 25. Applicants respectfully disagree. Applicants respectfully submit that Bardy merely discloses "an average from the group." See, e.g., paragraph [0067]. Nowhere does Bardy disclose, or even suggest, that "an average from the group" is based at least in part on an outcomes data group, wherein the outcomes data group comprises a plurality of the first outcomes data sets for the one or more indicators, as set forth in independent claims 1, 11, 19, 24 and 25. Moreover, Bardy fails to disclose, or even suggest that a norm is established based at least in part on one of the one or more medical procedures, as set forth in independent claims 1, 11, 19, 24 and 25. At best, Bardy merely discloses automatically collecting and analyzing patient information retrieved from an implantable medical device. See, e.g., paragraph [0042]. However, Bardy fails to disclose, or even suggest, that the

patient information collected from the implantable medical device is for one or more indicators associated with one of the one or more medical procedures, as set forth in independent claims 1, 11, 19, 24 and 25.

Regarding Seare, the Examiner further asserts that it would have been obvious to one of ordinary skill in the art to modify the system of Menzie by including features presented by Bardy in order to provide a convenience mechanism for user to assess medical services utilization in order to determine the best treatment for patients, as taught by Seare. Applicants respectfully disagree. Applicants respectfully submit that Seare is related to a system and a method for analyzing healthcare providers' billing patterns, enabling an assessment of medical services utilization pattern. See, e.g., column 5, lines 38-40. Therefore, it would NOT have been obvious to one of ordinary skill in the art to modify the physiological data collection system of Menzie by including features of an implantable medical device data collection system of Bardy in order to analyze healthcare providers' billing patterns, as taught by Seare.

At this point, Applicants would like to emphasize to the Examiner that, as stated in MPEP § 2141.02, a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed

invention. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). As confirmed in MPEP § 2145, it is improper to combine references where the references teach away from their combination. In re Grasselli, 713 F.2d 731, 218 USPQ 769, 779 (Fed. Cir. 1983).

In view of the foregoing, it is respectfully submitted that claims 1, 11, 19, 24, and 25 are allowable over Menzie, Bardy, and Seare, either alone or in combination.

Regarding claims 2-10, 12-18, 20-23, and 26-30 these claims are dependent upon independent claims 1, 11, 19, 24, and 25. Thus, since independent claims 1, 11, 19, 24, and 25 should be allowable as discussed above, claims 2-10, 12-18, 20-23, 26-30 should also be allowable at least by virtue of their dependency on independent claims 1, 11, 19, 24, and 25. Moreover, these claims recite additional features which are not disclosed, or even suggested, by the cited references taken either alone or in combination.

In view of the foregoing, it is respectfully requested that the aforementioned obviousness rejection of claims 1-3, 5-13, 15-19, 21-23, and 25-30 be withdrawn.

II. CONCLUSION

In view of the foregoing, it is respectfully submitted that the present application is in condition for allowance, and an early indication of the same is courteously solicited. The Examiner is respectfully requested to contact the undersigned by telephone at the below listed telephone number, in order to expedite resolution of any issues and to expedite passage of the present application to issue, if any comments, questions, or suggestions arise in connection with the present application.

To the extent necessary, a petition for an extension of time under 37 CFR § 1.136 is hereby made.

Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account No. 50-0206, and please credit any excess fees to the same deposit account.

Respectfully submitted,

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